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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/676,287 | 10/01/2003 | Richard Hochberg | Y03-076US | 7077 |

7590 05/21/2008

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| EXAMINER | |
|---|---|
| BADIO, BARBARA P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/21/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/676,287 | HOCHBERG, RICHARD | |
| | Examiner | Art Unit | |
| | Barbara P. Badio, Ph.D. | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 39-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 39-73 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/7/2008.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**First Office Action on the Merits**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 7, 2008 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 39-47 and 65-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "**treating the symtomology of menopause**" in a patient at risk for developing or with estrogen-sensitive cancer by administering the claimed compounds. The present specification discloses (a) the treatment of the symptomology of menopause and (b) the treatment of estrogen sensitive cancers (see for example, page 1, Field of the Invention; page 5, 2nd paragraph of the present specification). It lacks description of treating the symptoms of menopause in a patient at risk for developing or with estrogen-sensitive cancer and, thus, it lacks description of the instantly claimed invention.

The instant claims also encompass treatment of all of the symptoms of menopause by administering the claimed compound(s). However, because of the complexity of the human body and the differences in the underlining cause(s) of the various symptoms associated with menopause (for example, osteoporosis, vaginal atrophy, hot flashes, hypercholesterolemia, etc.) as well as the lack of showing in the medical art of the utilization of a single agent in the treatment of menopausal symptoms in general, the skilled artisan in the art at the time of the present invention would doubt the claimed compounds would be useful in the treatment method as recited by the instant claims. Therefore, in order to practice the claimed invention, the skilled artisan in the art at the time of the present invention would have to determine the effective of claimed compounds in the treatment of each symptom. Because of the knowledge in the medical art and the lack of guidance provided by the present specification, the quantity of experimentation necessary to practice the claimed invention would be undue.

5. Claims 39-47 and 57-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to (a) a method of treating the symptomology of menopause in a patient at risk for developing estrogen-sensitive cancer (see claims 39-47) and (b) a method of reducing the likelihood of a recurrence of breast cancer in a patient in need thereof comprising administering the claimed compounds.

In order to practice the claimed inventions, the skilled artisan in the art has to identify "a patient" at risk for developing estrogen-sensitive cancer or with the likelihood of a recurrence of breast cancer. The present specification lacks guidance as to how

one of skilled in the art would make said determination. It also lacks examples of treating said patient populations. The medical art teaches various treatments of the various menopausal symptoms but lacks showing of said treatment in patients "at risk" of developing estrogen-sensitvie cancer nor is there any showing of "reducing the likelihood" of recurrence of breast cancer. Therefore, in order to practice the claimed inventions, the skilled artisan in the art at the time of the present invention would have to determine a patient with menopausal symptoms "at risk for developing estrogen-sensitive cancer" or in need of "reducing the likelihood of a recurrence of breast cancer". Because of the knowledge in the medical art and the lack of guidance and/or examples in the present specification, the quantity of experimentation necessary to practice the claimed invention would be undue.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

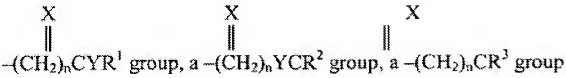
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 39-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

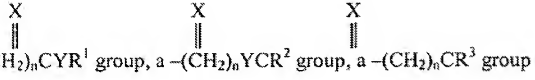
The instant claims are indefinite for the following reasons:

(a) Claims 39, 48, 57 and 65, the term "preferably" renders the claims indefinite because it is unclear whether the limitations following the term are part of the claimed invention.

(b) Claims 39 and 48 recite R is



and



, respectively. The above-mentioned groups are unclear because of the position of variable "=(X)".

(c) Claims 39, 48 and 65 recite "estrogen-sensitive cancer". The present specification sets forth "breast cancer" as an estrogen-sensitive cancer. However, apart from breast cancer, it is unclear what is encompassed by the above-mentioned phrase.

For these reasons, the metes and bound of the claimed invention is unclear and, thus, instant claims are indefinite.

***Claim Rejections - 35 USC § 103***

**8. The rejection of claims 1-6 and 13-38 under 35 103(c) over Van den Broek et al. (US 3,972,906) is made moot by the cancellation of the instant claims.**

9. Claims 39-56 and 65-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van den Broek et al. (US 3,972,906).

Van den Broek et al. teaches novel 11-substituted steroids of the estrane series such as 11β-methoxymethyl-ethinyl-estradiol (see the entire article, especially col. 1, line 19 - col. 2, line 27). The reference teaches the compounds possess several properties including estrogenic and progestational properties and are useful in the treatment of estrogen-deficiency syndromes (see col. 2, lines 29-53).

The instant claims differ from the reference by reciting the treatment of the symptoms of menopause or breast cancer. However, the art teaches the use of estrogenic compounds in the treatment of menopausal symptoms as well as treatment of breast cancer (see for example, Goodman and Gilman, seventh edition, pages 1421-1423; US 6,268,361, Abstract; US 2001/0025051; section 0003; US 4,617,298, col. 3, lines 25-31). Therefore, the utilization of the compounds of Van den Broek et al. in the treatment of disorders as recited by the instant claims would have been prima facie obvious to the skilled artisan in the art at the time of the invention. The motivation is based on the teaching by Van den Broek et al. of the estrogenic property of the prior art compounds and its use in treating estrogen-deficiency syndromes as well as the

knowledge in the art that menopause is due to estrogen deficiency and the utilization of estrogenic compounds in the treatment of menopausal symptoms and breast cancer.

Claims 39-47 and 65-73 further differ from the reference by reciting treatment of the symptoms of menopause in a patient "at risk for developing estrogen-sensitive cancer" or "with estrogen-sensitive cancer". However, the claimed invention is a method of treating menopausal symptoms. The fact that the patient is at risk or has an estrogen-sensitive cancer is irrelevant to the treatment of menopausal symptoms. The skilled artisan would have the reasonable expectation that menopausal symptoms would be treated irrespective of patient population, i.e., whether said menopausal symptom(s) is shown in a patient with/without or at risk or not of estrogen-sensitive cancer.

***Response to Arguments***

10. Applicant argues the instant claims are patentable over the cited prior art because of its teaching of exclusively estrogenic activity of the disclosed compounds not SERM activity as disclosed by the present invention. Applicant's argument was considered but not persuasive for the following reasons.

First, the reference does not teach the prior art compounds are "exclusively estrogenic". As indicated above and in the previous Office Actions, the reference teaches several properties of which "estrogenic" is one of said properties (see for example, col. 2, lines 29-32).

Secondly, the issue is not whether the reference discloses the compounds are SERM (selective estrogen receptor modulators). The issue is whether the prior art teaches similar compounds and makes obvious the utilization of said compounds as presently claimed. The examiner's position is that the prior art compounds are encompassed by the instant claims. For example, 11β-methoxymethyl-ethinyl-estradiol as exemplified by the cited reference is anticipated by the instant claims (see for example, claim 45). The reference teaches said compound is useful in treating estrogen-deficiency syndromes and the teaches the utilization of estrogenic compounds in treating menopausal syndromes and breast cancer. Based on the knowledge in the art of the use of estrogenic compounds and the teachings of the cited reference, the utilization of the prior art compounds as claimed by the present invention would be prima facie obvious. It is noted that similar compounds would have similar properties and, thus, the prior art compounds would inherently have the properties discussed by the present specification.

***Telephone Inquiry***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612